

CLAIMS

Therefore, having thus described the disclosure, at least the following is claimed:

1 1. An isolated polynucleotide comprising a polynucleotide selected from: a polynucleotide
2 sequence set forth in SEQ ID NO: 1 (C307YhGALE) or a degenerate variant of the SEQ ID
3 NO: 1; a polynucleotide sequence at least 90% identical to the polynucleotide sequence set forth
4 in SEQ ID NO: 1; a polynucleotide sequence at least 75% identical to the polynucleotide
5 sequence set forth in SEQ ID NO: 1; and a polynucleotide sequence at least 50% identical to the
6 polynucleotide sequence set forth in SEQ ID NO: 1.

1 2. A polypeptide selected from: an amino acid sequence set forth in SEQ ID NO: 2
2 (C307YhGALE), or conservatively modified variants thereof; an amino acid sequence that is at
3 least 90% identical to SEQ ID NO: 2; an amino acid sequence that is at least 75% identical to
4 SEQ ID NO: 2; and an amino acid sequence that is at least 50% identical to SEQ ID NO: 2.

1 3. A vector comprising the isolated polynucleotide of claim 1.

1 4. The vector of claim 3 wherein the vector is pPIC3.5K .

1 5. An isolated host cell comprising the vector of claim 3.

1 6. The isolated host cell of claim 5 wherein the host cell is selected from: *Pichia pastoris*,
2 *Saccharomyces cerevisiae*, *Schizosaccharomyces pombe*, and *Escherichia coli*.

1 7. The isolated host cell of claim 6 wherein the host cell is *Pichia pastoris*.

1 8. A process for producing a polypeptide comprising culturing the host cell of claim 7 under
2 conditions sufficient for the production of the polypeptide where the polypeptide has the
3 characteristics that the polypeptide is capable of UDP-gal/UDP-glc interconversion and
4 substantially incapable of UDP-galNAc/UDP-glcNAc interconversion.

1 9. The process of claim 8 wherein the polypeptide is the polypeptide of claim 2.

1 10. A cell line transfected with an expression vector comprising a polynucleotide selected
2 from: a polynucleotide sequence set forth in SEQ ID NO: 1(C307YhGALE) or a degenerate
3 variant of the SEQ ID NO: 1; a polynucleotide sequence at least 90% identical to the
4 polynucleotide sequence set forth in SEQ ID NO: 1; a polynucleotide sequence at least 75%
5 identical to the polynucleotide sequence set forth in SEQ ID NO: 1; and a polynucleotide
6 sequence at least 50% identical to the polynucleotide sequence set forth in SEQ ID NO: 1,
7 encoding a polypeptide having the characteristics that the polypeptide is capable of UDP-
8 gal/UDP-glc interconversion and substantially incapable of UDP-galNAc/UDP-glcNAc
9 interconversion.

1 11. The cell line of claim 10 wherein the polypeptide is selected from: an amino acid
2 sequence set forth in SEQ ID NO: 2 (C307YhGALE), or conservatively modified variants
3 thereof; an amino acid sequence that is at least 90% identical to SEQ ID NO: 2; an amino acid
4 sequence that is at least 75% identical to SEQ ID NO: 2; and an amino acid sequence that is at
5 least 50% identical to SEQ ID NO: 2.

1 12. The cell line of claim 10 wherein the expression vector is pCDNA3.

1 13. The cell line of claim 10 wherein the cell line is GALE deficient.

1 14. The cell line of claim 13 wherein the cell line is *ldlD*.

1 15. A vector comprising an isolated polynucleotide selected from: a polynucleotide sequence
2 set forth in SEQ ID NO: 3 (WTeGALE), or a degenerate variant of the SEQ ID NO: 3; a
3 polynucleotide sequence at least 90% identical to the polynucleotide sequence set forth in SEQ
4 ID NO: 3; a polynucleotide sequence at least 75% identical to the polynucleotide sequence set
5 forth in SEQ ID NO: 3; and a polynucleotide sequence at least 50% identical to the
6 polynucleotide sequence set forth in SEQ ID NO: 3.

1 16. The vector of claim 15 wherein the vector is pPIC3.5K.

1 17. An isolated host cell comprising the vector of claim 15.

1 18. The isolated host cell of claim 17 wherein the host cell is selected from: *Pichia pastoris*,
2 *Saccharomyces cerevisiae*, *Schizosaccharomyces pombe*, and *Escherichia coli*.

1 19 The isolated host cell of claim 18 wherein the host cell is *Pichia pastoris*.

1 20. A process for producing a polypeptide comprising culturing the host cell of claim 19
2 under conditions sufficient for the production of the polypeptide where the polypeptide has the
3 characteristics that the polypeptide is capable of UDP-gal/UDP-glc interconversion and
4 substantially incapable of UDP-galNAc/UDP-glcNAc interconversion.

1 21. The process of claim 20 wherein the polypeptide is selected from: an amino acid
2 sequence set forth in SEQ ID NO: 4, or conservatively modified variants thereof; an amino acid
3 sequence that is at least 90% identical to SEQ ID NO: 4; an amino acid sequence that is at least

75% identical to SEQ ID NO: 4; and an amino acid sequence that is at least 50% identical to
SEQ ID NO: 4

22. A cell line transfected with an expression vector comprising a polynucleotide selected from: a polynucleotide SEQ ID NO: 3 (WTeGALE) or a degenerate variant of the SEQ ID NO: 3; a polynucleotide sequence at least 90% identical to the polynucleotide sequence set forth in SEQ ID NO: 3; a polynucleotide sequence at least 75% identical to the polynucleotide sequence set forth in SEQ ID NO: 3; and a polynucleotide sequence at least 50% identical to the polynucleotide sequence set forth in SEQ ID NO: 3 encoding a polypeptide having the characteristics that the polypeptide is capable of UDP-gal/UDP-glc interconversion and substantially incapable of UDP-galNAc/UDP-glcNAc interconversion.

23. The cell line of claim 22 wherein the polypeptide is selected from: an amino acid sequence set forth in SEQ ID NO: 4 (WTeGALE), or conservatively modified variants thereof; an amino acid sequence that is at least 90% identical to SEQ ID NO: 4; an amino acid sequence that is at least 75% identical to SEQ ID NO: 4; and an amino acid sequence that is at least 50% identical to SEQ ID NO: 4

24. The cell line of claim 22 wherein the expression vector is pCDNA3.

25. The cell line of claim 22 wherein the cell line is GALE deficient.

26. The cell line of claim 25 wherein the cell line is *ldlD*.

27. A method of culturing the cell line of claim 10 in the absence of galactose to produce glycoproteins having N-linked modifications with substantially no O-linked modifications.

- 1 28. A method of culturing the cell line of claim 22 in the absence of galactose to produce
2 glycoproteins having N-linked modifications with substantially no O-linked modifications.